



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0901]

Meunerie Sawyerville, Inc.; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying a request for a hearing submitted by Meunerie Sawyerville, Inc. (Meunerie Sawyerville) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Meunerie Sawyerville for 5 years from importing articles of food or offering such articles for import into the United States. FDA bases this order on a finding that Meunerie Sawyerville was convicted of felony offenses for conduct relating to the importation of food into the United States. In determining the appropriateness and period of Meunerie Sawyerville's debarment, FDA has considered the relevant factors listed in the FD&C Act. Meunerie Sawyerville has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application by Meunerie Sawyerville for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA-2017-N-0901. An application will be placed in the docket and, unless submitted as "Confidential Submissions,"

publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathan R. Sabel, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 301-796-8588.

SUPPLEMENTARY INFORMATION:

I. Background

On November 9, 2015, in the U.S. District Court for the District of Vermont, Meunerie Sawyerville pled guilty to two felony counts related to the importation of food into the United States. Both offenses occurred from on or about September 12, 2012, to on or about January 15, 2013. With respect to Count One, Meunerie Sawyerville admitted to knowingly and intentionally making and using a false writing that contained a materially fictitious statement in a matter within the jurisdiction of the executive branch of the United States government in violation of 18 U.S.C. 1001(a)(3) "by submitting a false Automated Commercial Environment Manifest listing a fictitious importer, namely, Ted Taft, and presenting such documents to Customs and Border Protection [Customs] officials...knowing and believing that Ted Taft was not the true importer of the goods" described in the manifest. With respect to Count Two, Meunerie Sawyerville admitted to causing the introduction of an adulterated drug (i.e., cattle feed containing monensin) into interstate commerce with the intent to defraud and mislead in violation of sections 301(a), 303(a)(2), and 501(a)(6) of the FD&C Act (21 U.S.C. 331(a), 333(a)(2), and 351(a)(6)). Under section 501(a)(6), a drug is adulterated if it is an animal feed bearing or containing a new animal drug that is unsafe within the meaning of the FD&C Act.

Under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)), FDA is authorized to debar Meunerie Sawyerville from importing articles of food or offering food for import into the United States based on a finding, under section 306(b)(3)(A) of the FD&C Act,

that Meunerie Sawyerville was convicted of a felony for conduct relating to the importation of food into the United States. By letter dated July 21, 2017, the Office of Regulatory Affairs (ORA) notified Meunerie Sawyerville of a proposal to debar it for 5 years from importing articles of food or offering such articles for import into the United States and provided an opportunity for Meunerie Sawyerville to request a hearing. In proposing a debarment period, ORA weighed the considerations in section 306(c)(3) it considered applicable to Meunerie Sawyerville's offenses, concluded that each of these felony offenses independently warranted a 5-year period of debarment, and proposed that these debarment periods be served concurrently under section 306(c)(2)(A). By letter dated August 14, 2017, Meunerie Sawyerville requested a hearing on the proposal.

The Director of the Office of Scientific Integrity (OSI) has reviewed Meunerie Sawyerville's request for a hearing, as well as the materials offered in support, and finds that Meunerie Sawyerville has not established a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact for resolution at a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). OSI has considered Meunerie Sawyerville's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

Meunerie Sawyerville does not dispute that it is subject to debarment under section 306(b)(1)(C) of the FD&C Act because it committed two felony offenses related to the importation of food. Nor does Meunerie Sawyerville dispute any of ORA's factual findings

contained in the proposal to debar. Further, Meunerie Sawyerville does not dispute ORA's conclusion based on these findings that both the nature and seriousness of the offenses and the nature and extent of Meunerie Sawyerville management's participation in the offenses are both considerations favoring debarment.

Against this backdrop, Meunerie Sawyerville argues only: (1) that ORA failed to consider as an applicable factor, under section 306(c)(3)(D) of the FD&C Act, the operational changes Meunerie Sawyerville contends it has made that would prevent it from shipping adulterated animal feed again in the future, specifically, discontinuing the use of monensin in its animal feed, (2) that voluntary mitigation of the offenses should not count as an unfavorable consideration under section 306(c)(3)(C) because Meunerie Sawyerville pled guilty and no specific harm occurred that Meunerie Sawyerville could mitigate, and (3) that debarment is not an appropriate remedy when customers are not defrauded and when debarment would hurt Meunerie Sawyerville's business.

Section 306(c)(3) requires FDA to consider, "where applicable," certain factors "[i]n determining the appropriateness and the period of debarment" for debarment under section 306(b)(3) of the FD&C Act. The proposal to debar Meunerie Sawyerville set forth five potentially applicable considerations for debarment actions related to food importation imposed under section 306(b)(1)(C): (1) the nature and seriousness of the offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C); (4) the extent that ownership, management, or operations changes have corrected the causes of the offense and provide reasonable assurances that the offense will not recur under 306(c)(3)(D); and (5) prior convictions involving matters within the

jurisdiction of FDA under section 306(c)(3)(F). In its proposal, ORA found that the first three considerations weigh in favor of debaring Meunerie Sawyerville and noted that the fifth consideration weighs against debarment because the Agency was unaware of any prior convictions involving matters within the jurisdiction of FDA. ORA found the fourth consideration inapplicable.

Meunerie Sawyerville's now represents that it no longer ships animal feed containing monensin and argues that changes in its operations should be counted as a consideration weighing against debarment under section 306(c)(3)(D). Beyond removing monensin from its production process, Meunerie Sawyerville points to no other changes in ownership, management, or operations that would address the causes of the offenses and provides no other reasonable assurance that the criminal conduct underlying the offenses will not recur. As ORA's proposal finds and Meunerie Sawyerville concedes, the same management remains in charge at Meunerie Sawyerville, including president and owner Yves Bolduc, who Meunerie Sawyerville admits devised and executed the fraudulent scheme forming the basis for the offenses:

[A]fter the medicated feed at issue was sampled at the border, found to contain monensin at a concentration above that allowed by FDA, and the driver was ordered to warehouse the feed pending further testing from FDA, Mr. Bolduc instructed the driver to deliver the feed to a Vermont farmer as planned, without informing the farmer that the feed had been sampled and ordered held by FDA. Mr. Bolduc then engineered a plan that a sham shipment of similar-looking cattle feed cross the border under false Customs documentation to be stored on an unrelated piece of land in Vermont until requested for redelivery by Customs and Border Protection. Upon request by Customs and Border Protection, Mr. Bolduc ordered that the sham shipment be presented for redelivery, accompanied by the fictitious documentation, offering up the sham shipment feed to the U.S. government as the held tainted feed.

Meunerie Sawyerville has admitted to knowingly and intentionally orchestrating this presentation of false documents to Customs as part of a larger scheme to defraud government regulators about the nature of a shipment offered for import and to introducing adulterated

product into interstate commerce with the intent to defraud and mislead. Meunerie Sawyerville does not dispute this conduct.

Meunerie Sawyerville also argues in its hearing request that the majority of its business going forward, if Meunerie Sawyerville is not debarred, would involve offering animal feed for import into the United States from Canada, necessarily requiring Meunerie Sawyerville to provide Customs with an ongoing stream of information about its products in the future. As an FDA-regulated product, animal feed can become adulterated in numerous ways, not merely through the addition of too much monensin (see, generally, section 402 of the FD&C Act (21 U.S.C. 342)). In addition to adulteration, there are also many other reasons an unscrupulous importer might attempt to deceive Customs. Any regular importer of food will be required to submit import documents to Customs repeatedly that detail the nature, value, quantity, and condition of product offered for import. As a result, simply removing monensin from Meunerie Sawyerville's process does not sufficiently address the causes of the offenses and provides little assurance that Meunerie Sawyerville would handle future food import matters without resorting to the knowing and intentional deception of government regulators and the introduction of adulterated product that forms the basis of these offenses. Therefore, even assuming as true that Meunerie Sawyerville has stopped adding monensin to its animal feed, Meunerie Sawyerville has not sufficiently corrected the causes that resulted in the offenses and has not provided reasonable assurances that these offenses will not recur. As a result, the Director of OSI finds that the consideration in section 306(C)(3)(D) should not be considered as weighing against debarment for these offenses.

Next, Meunerie Sawyerville argues that the nature and extent of steps taken to mitigate the impact of its offenses on the public under section 306(c)(3)(C) of the FD&C Act should be a

consideration weighing against debarment. Meunerie Sawyerville argues that there was no evidence that specific members of the public were harmed such that mitigation of that harm was possible and that it pled guilty as the only possible mitigation step. OSI disagrees that Meunerie Sawyerville's actions suggest significant voluntary mitigation of the harm related to the offenses at issue. Although the government exposed Meunerie Sawyerville's offenses in progress and thereby prevented harm to any specific victims for the offenses at issue, other voluntary mitigation efforts were available to Meunerie Sawyerville beyond simply pleading guilty when apprehended. Indeed, with respect to voluntary mitigation for the offense in Count Two, Meunerie Sawyerville devised the fraudulent scheme underlying the offense in Count One to compound, rather than mitigate, its earlier criminal conduct of shipping an adulterated product to its customer in Vermont. Rather than admitting the earlier misconduct to Customs and FDA to mitigate any harm from its earlier tainted shipment and avoid continuing to undermine the government's ability to regulate imports, Meunerie Sawyerville engaged in additional criminal conduct and devised the sham shipment and fictitious documents that formed the basis for the offense in Count One. Further, with respect to Count One itself, because this offense was devised to conceal other criminal conduct, the primary opportunity to mitigate the associated harm to the government's regulatory authority occurred throughout Meunerie Sawyerville's efforts to devise and execute the scheme described in Count One. Rather than take steps to mitigate the harm from the earlier criminal offense, Meunerie Sawyerville chose to take affirmative steps to compound that harm. In this context, Meunerie Sawyerville deserves no credit for a guilty plea when its scheme was uncovered. Therefore, considering the facts and the context of these offenses, the Director of OSI finds that the extent of voluntary efforts to mitigate

the impact of these offenses should not be considered in favor of Meunerie Sawyerville under section 306(c)(3)(C).

Lastly, Meunerie Sawyerville argues that debarment is inappropriate as a matter of policy because it would harm Meunerie Sawyerville's business and force its customers to consider other suppliers for their animal feed. As already noted, a hearing will not be granted on issues of policy such as these (see 21 CFR 12.24(b)). Also, the considerations Meunerie Sawyerville raises, such as the impact of debarment on Meunerie Sawyerville's business, are not appropriate considerations under section 306(c)(3) for determining the length of a period of debarment. Finally, the remedial purpose of the debarment statute is designed to accomplish exactly the result to which Meunerie Sawyerville objects by protecting the public from food from importers whose criminal conduct demonstrates, based on the applicable considerations, that they warrant debarment. As such, these arguments do not support Meunerie Sawyerville's request for a hearing on this matter.

III. Findings and Order

Because OSI has assumed as true that Meunerie Sawyerville has discontinued using monensin in its process and Meunerie Sawyerville raises no other arguments that would present genuine and substantial issues of fact that would require resolution at an evidentiary hearing, Meunerie Sawyerville's request for an evidentiary hearing is denied.

Considering all applicable factors under 306(c)(3) of the FD&C Act, OSI concurs with ORA's proposal that a 5-year period of debarment for each offense is warranted. On this record, OSI finds that the nature and seriousness of the offenses and the nature and extent of Meunerie Sawyerville management's participation in the offenses are factors weighing heavily in favor of debarment. For the reasons already discussed, even assuming Meunerie Sawyerville has

discontinued using monensin in its operations, OSI finds that operational change insufficient under section 306(c)(3)(D) to demonstrate correction of the causes of these offenses and to provide reasonable assurances that the offenses will not recur. Further, even after taking into account Meunerie Sawyerville's guilty plea under section 306(c)(3)(C), OSI finds that Meunerie Sawyerville's conduct related to this consideration weighs in favor of debarment. Although Meunerie Sawyerville's lack of a prior conviction under 306(c)(3)(F) is a factor weighing against debarment, this consideration is substantially outweighed by the nature and seriousness of the offenses, the nature and extent of management's participation in the offenses, and the nature and extent of voluntary steps to mitigate the impact of the offenses on the public. Therefore, considering all of these factors together and the record as a whole, OSI finds that a 5-year period of debarment is warranted for each offense.

Therefore, the Director of OSI, under section 306(b)(3)(A) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds that Meunerie Sawyerville has been convicted of a felony for conduct relating to the importation of food into the United States. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate for each of these felony offenses. These periods will run concurrently under section 306(c)(2)(A). As a result of the foregoing findings, Meunerie Sawyerville is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, applicable (see DATES). Under section 301(cc) of the FD&C Act, the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Meunerie Sawyerville is a prohibited act.

Dated: February 26, 2018.

George M. Warren,

Director, Office of Scientific Integrity.

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